

If there is a question about an indemnity, who should we contact?

Email the general Bellberry inbox bellberry@bellberry.com.au or call Bellberry on 08 8361 3222 and the query will be forwarded to a HREC Officer.

I can see Bellberry's details on the template, what part do I complete?

From: Please include the sponsors full name, address and ABN. (remove unnecessary template text).

RE: Please include the full title of the Protocol as it is in the application (this must match the exact title of the Protocol and the application) (remove unnecessary template text).

In paragraph 1: Please insert the description that relates to "the Participants" of your study in the text prior to ("the Participants") and remove the unnecessary template text in brackets – for example remove (patients of name of hospital....).

Please insert the name of the Principal Investigator (s) and remove the text (name of investigator(s) prior to (the Investigator).

Save the document and follow your internal procedures for execution of the document.

Can I write an abbreviated title on the Indemnity?

No. Please include the full title of the Protocol as it is in the application. It must match the exact title of the Protocol and the application.

Our site is the lead site. Our HREC only indemnity lists 6 sites, however, only 5 have submitted applications. What do I do?

For hard copy indemnities, the Bellberry signatory will strike through the site for which an application has not been submitted and initial the change. If/when the additional site submits their application:

- the lead site will need to provide an updated HREC indemnity listing the previously removed site, or;
- the additional site may submit a HREC indemnity listing their site only.

For electronic indemnities, the indemnity will be returned to the site/sponsor to be amended. Bellberry is unable to edit the electronic forms.

Can I scan a copy of a document and then upload it into an e-signature platform such as Adobe?

No. The signature must be verifiable. A scanned document cannot be accepted as the signature will not have the electronic validation mark. An electronic indemnity will be required to be signed through the electronic platform used.

I am a research organisation contracted by a government department to undertake a research project, who should provide the HREC indemnity?

It will need to be determined between the research organisation and the government department who will take on responsibility for insurances and indemnities. Whoever is taking on the responsibility will need to provide the HREC Indemnity. The organisation on the indemnity needs to match the insured organisation.

I am a research organisation contracted by a government department to undertake a research project, and will provide the HREC indemnity, do I need a Standard indemnity?

No, a Standard indemnity is not required. This will generally be covered through the agreement in place between the government department and the research organisation.

My study is non-sponsored and is investigator led, do I need to provide a HREC indemnity?

If there is no sponsor for a study and the Principal Investigator/site has confirmed that they are taking on responsibility of insurance and indemnity, the HREC Indemnity will need to be between the investigator/site and Bellberry. The indemnity must exist between the two parties in the same way as it would for a sponsored study. The investigator or investigator's employer may take the responsibility of the sponsor.

If an electronic HREC Indemnity can't be signed electronically by Bellberry (e.g. the sender hasn't created a signature field for Bellberry) can this be printed and signed manually (if there is a signature verification stamp)?

Yes, if agreeable by the site/sponsor.

Does Bellberry allow counterpart clauses to be added to the HREC Indemnity?

Yes. We recommend submitting any proposed changes or additions to the indemnity to Bellberry as soon as possible. Discussion on the changes can happen in parallel to the study review. Where possible, the Indemnity should be part of the initial submission. If it is not available at the point of submission, it will be required to be finalised before approval of the study is completed. Once agreed upon, the sponsor can use this same form of indemnity with Bellberry for any future studies where the same conditions apply.

When would the non-patient volunteer clause in paragraph 1 of the Indemnity be used?

If a research institution has healthy volunteers that would not be considered 'patients' of the organisation, they may complete their HREC Indemnity in the following manner:

The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving non-patient volunteers ("the Participants") to be conducted by ("the Investigator").

I am unsure how to set up the indemnity in DocuSign, what do I do?

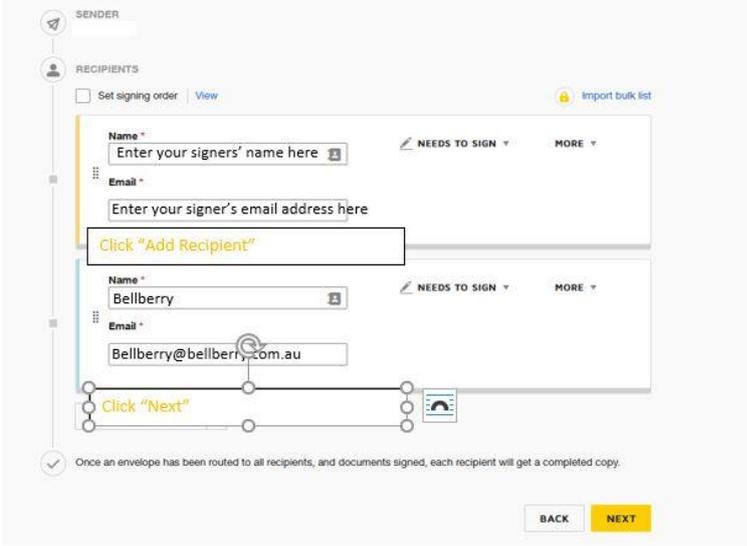
Open DocuSign. On the Home page, click "START NOW"

Upload and attach the correctly edited HREC Indemnity word document.

CLICK "NEXT" (DO NOT tick I am the only signer)

Create a signing cycle.

Please add a signature for the delegated sponsor signatory and then add another recipient for Bellberry bellberry@bellberry.com.au. See the below image.



Note:
Set the signing order. Make sure Sponsor is number 1 recipient.

Bellberry is number 2 recipient.

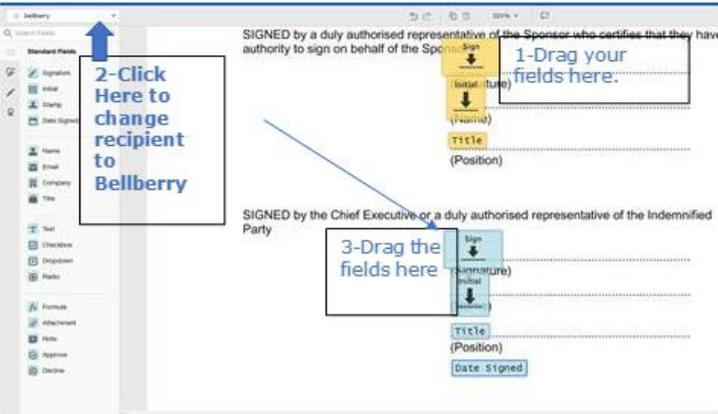
Insert Signatory Fields.

You will need to insert the signatory fields in the very last page so that the recipients can electronically sign.

The top signature section is for the sponsor details. Drag the fields on the left to your signing area. Signature. Initial. Title.

Click the top left menu button to change the recipient to Bellberry then click and drag the fields to the bottom signatory section.

Bellberry must be able to edit the Name and Title field.



Click send document.

An email notification will be sent to the first recipient for signing. Once this has been completed an email notification will be sent to the second recipient (Bellberry) for signing.